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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,914	04/30/2001	Bozidar Ferek-Petric	P-8191	9906

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EXAMINER
OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

05

Office Action Summary	Application No.	Applicant(s)	
	09/843,914	FEREK-PETRIC, BOZIDAR	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/30/04 (Amendment)*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Examiner appreciates the Applicant highlighting citations in the specification and figures associated with the amendment of 6/13/03. The Applicant's arguments are convincing regarding the 35 U.S.C. 112 rejection of record, hence the 35 U.S.C. 112 rejections of record are withdrawn.

Claim Rejections - 35 USC § 103

2. Claims 1 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Alt (US 5458622) in view of Bardy et al. (US 5257621) for the reasons of record and the discussion below.

Alt discloses an apparatus and method, substantially as claimed, to provide multiple threshold and therapy levels to successfully treat tachycardia (figure 4; col. 9 @ 38-47; col. 9 @ 60 – col. 10 @ 19). The heart rate threshold increases and decreases based on the non-ECG sensor output (hemodynamic parameter / physiologically-sensed condition / hemodynamic measurement). When the heart rate (counted interval(s)) is equal to or greater than a threshold or less than the threshold, a second threshold is adjusted and therapy is provided, as needed, to treat the tachycardia (col. 11 @ 18-49; col. 12@ 5-28; col. 13 @ 7-11; col. 14 @ 44-51 and 56-61; col. 15 @ 40-51). The intervals are consecutive, as non-consecutive intervals indicate dysrhythmia (col. 5 @ 50-57; col. 6 @ 64 – col. 7 @ 5).

Resetting the threshold can comprises increasing or decreasing the threshold, based on the blood pressure feedback or based on a predetermined relationship between the

physiologically-sensed condition. Inherently, the threshold is reduced with a reduction in blood pressure (col. 5 @ 45-49; col. 11 @ 35-44).

The hemodynamic sensor, the activity sensor (34), can also be an indirect sensor such as a sensor of blood pressure or a blood flow rate sensor (col. 3 @ 12-26; col. 7 @ 64 – col. 8 @ 3; col. 9 @ 47-52).

As to identification and treatment of hemodynamically stable and unstable tachycardia, Alt discloses the use of two independent sensors, an ECG sensor and a complementary non-ECG sensor (blood pressure sensor) used in combination to provide a clear indication of an individual's condition so proper tiered therapy can be provided given stability or lack of stability of the blood pressure at a given level (col. 3 @ 12-26; col. 3 @ 63 – col. 4 @ 19; col. 10 @ 35-46; col. 11 @ 40-49; col. 12 @ 5-21). US 5342404 to Alt, incorporated by reference (col. 3 @ 13-19), elaborates on therapy control based on hemodynamic function as represented by blood pressure (col. 6 @ 21-42).

As discussed in the previous two paragraphs, Alt discloses the claimed invention except for: using controller circuitry to initiate an adjustable number of intervals detected (NID) threshold, resetting the adjustable NID threshold based on at least a first measurement of a value (hemodynamic parameter / physiologically-sensed condition / a predetermined relationship / a hemodynamic measurement / a blood pressure measurement), and detecting tachycardia if the consecutive number of intervals satisfies / is equal to or greater than / the adjustable NID threshold.

Bardy et al. disclose an apparatus for detection of, discrimination between and treatment of tachycardia and fibrillation and teach the following elements:

- use of control circuitry to identify a single value that detects tachyarrhythimas,
- use of subsequent values to appropriately adjust the threshold level and therapy, wherein the threshold is adjusted by varying the number of intervals for detection of tachycardia in each tachycardia rate zone, the threshold being a potentially unique number of intervals for each tachycardia rate zone, and
- use of measurements associated with the current heart rate intervals for adjusting the number of intervals required to for detection of tachycardia, the measurements read to be a hemodynamic parameter /physiologically-sensed condition / hemodynamic measurement, , hence teaching the invoking of different NIDs based on the blood pressure .

Modification of the PCD as taught by Alt with the elements above is motivated because use of less stringent criteria for tachycardia detection as the tachycardia event progresses enables the patient to receive more rapid effective treatment (col. 17 @ 22-36; col. 18 @ 1-43; col. 19 @ 4-7).

The Applicant arguments regarding the 35 U.S.C. 103(a) rejection of record, filed 3/ 30/04, have been fully considered but they are not convincing.

The Applicant asserts the complementary sensor (col. 3 @ 20) also defined as an indirect sensor of physical exercise (col. 3@ 24-25) that can be a blood pressure detector/ sensor

(col. 3 @ 25) is not a blood pressure detector because it is an indirect sensor of physical exercise. The Examiner disagrees. Claims 1 and 20 comprise a blood pressure sensor that senses changes/ substantial drops in blood pressure (col. 3 @ 13-26), hence these elements are deemed to be taught by Alt. In addition, as noted in the rejection of record, US 5342404 to Alt, incorporated by reference into Alt (US 5458622) (col. 3 @ 13-19), elaborates on therapy control based on hemodynamic function as represented by blood pressure (col. 6 @ 21-42).

The Applicant asserts the Examiner fails to supply any reference for the assertion that "The heart rate threshold increases and decrease based on non-ECG sensor output (hemodynamic parameter / physiologically-sensed condition / hemodynamic measurement). The Examiner disagrees. References associated with the final portion of the paragraph from which this sentence is taken are provided at the end of the paragraph, hence the following previous noted citations all support this teaching by Alt: col. 5 @ 45-49; col. 11 @32-49; col. 12 @ 5-28 and col. 13 @ 7-11.

The Applicant asserts "the Examiner has only cited albeit colored passages from the background of Alt". The Examiner disagrees. In the rejection of record, the Examiner has fairly represented the invention of Alt as it related to the instant invention by noting 2 citations from the Background section of Alt and 13 citations from the Summary of the Invention section of Alt.

The Applicant asserts "No citation contained in the rejection appears to relate to any portion of the invention Alt considered the invention! ". The Examiner disagrees. The citations cited by the Examiner define the invention/ teaching of Alt.

In response to the Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, a motivation to combine the reference was supplied in the rejection of record, the reason to combine being supported by the passages that were cited in the rejection. The reason to combine is repeated here: Modification of the PCD as taught by Alt with the elements above is motivated because use of less stringent criteria for tachycardia detection as the tachycardia event progresses enables the patient to receive more rapid effective treatment (col. 17 @ 22-36; col. 18 @ 1-43; col. 19 @ 4-7).

In response to the Applicant's argument that the references fail to show certain features of the Applicant's invention, it is noted that the features upon which the Applicant relies (i.e., direct hemodynamic measurements, appropriate blood pressure sensors, signal handling, any direct relationships between heart rate, blood pressure and tachycardia status) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Drawings

3. Figure 8 is objected to because in blocks 414 and 424 it appears "Hemodinam." should be --Hemodynam.--.

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
6/18/04

Angela D. Sykes

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